REMARKS

Claims 1, 6, 7, 10, 16, 20, and 24-28 are currently being amended. Claims 29-38 are added. Support for new claims 29-38 can be found in the specification at paragraph [0008], paragraph [0021], paragraph [0034], paragraph [0037], and paragraph [0038].

The undersigned wishes to thank the examiner and Primary Examiner Ferris for the courtesy extended to the undersigned and Alex Bangs in the interview of 6 June 2006. The interview summary prepared by the examiner accurately reflects the substance of the interview.

Claims 1-38 are now pending in this application. In view of the amendments and following remarks, Applicants respectfully request reconsideration of the present application and submit that the application is in condition for allowance.

I.   Objection to Claims 10, 16, and 20

The Examiner objected to claims 10, 16, and 20 because of the following informalities: 1) a quote in the middle of the preamble, and 2) the preamble contains two transition phrases "further wherein" and "comprising." The quote in the preamble has been removed. Claims 10, 16, and 20 have further been amended to include a single transitional phrase "comprising."

The Examiner further respectfully suggests amending the related claim preambles. According to MPEP 2106 ¶ IV.B.1(a), "a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory." Applicants assert that claims 10, 16, and 20 are directed to a computer-readable medium product, and that the preamble recites the statutory subject matter of a computer-readable medium encoded with instructions.

II.   Rejection of Claims Under 35 U.S.C. § 112

In the Office Action, Examiner makes a rejection under 35 U.S.C. § 112 without identifying any particular claim as being subject to this rejection. Applicants respectfully traverse this rejection.

On page 2, of the Office Action dated 2/9/2006, the Examiner states:

> Note the definition of "simulation":
>
> Simulation. **Imitating or estimating how events might occur in a real situation.** It can involve complex mathematical modeling, role playing without the aid of technology, or combinations. ....
> (http://ag.arizona.edu/futures/home/glossary.html)

(Emphasis in original). On page 6, of the Office Action dated 2/9/2006, the Examiner further states:

> The term "simulation" is used by the claims to mean "integration", while the accepted meaning is **Imitating or estimating how events might occur in a real situation."** The term is indefinite because the specification does not clearly redefine the term.

(Emphasis in original).

In paragraph [0030] of the present application, Applicants explicitly define the term "simulation" as follows:

> The term "simulation" is used herein to mean the numerical or analytical integration of a mathematical model. For example, simulation can mean the numerical integration of the mathematical model of the biological state defined by the above equation, i.e. $dx/dt=f(x, p, t)$.

This definition does not conflict with the meaning attributed by those skilled in the art or the meaning provided by the Examiner.

An Applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994), and *Vitronics Corp. v. Conceptronic Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Where an explicit definition is provided by the applicant for a term,

that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301 (Fed. Cir. 1999). Any special meaning assigned to a term "must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention." *Multiform Desiccants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998).

Numerical or analytical integration of a mathematical model is an accepted method for "imitating or estimating how events might occur in a real situation." While Applicant does not concede that the definition presented by the Examiner represents the exact common and ordinary meaning of the term "simulation", Applicant submits that the explicit definition provided in the specification is not in conflict with any customary meaning for the term. Applicants respectfully assert that the term "simulation" has been clearly defined in the specification in a manner that would be understood by a person of skill in the art of simulation. As a result, the definition is not indefinite. Therefore, Applicants respectfully request withdrawal of the rejection of unspecified claims under 35 U.S.C. § 112.

III.   Rejection of Claims 1-9, 20, and 25-28 Under 35 U.S.C. § 102(e)

In the Office Action, claims 1-9, 20, and 25-28 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,272,480 to Tresp et al (hereinafter "Tresp"). Claims 1, 7, and 20 are amended to clarify that a simulation of glucose metabolism in the context of multiple macronutrient metabolism refers to a simulation of glucose metabolism, or a plurality of biological processes, comprising a representation of metabolism of two macronutrients selected from the group consisting of carbohydrate metabolism, fat metabolism and protein metabolism. Claims 25 and 27 are amended to clarify that the simulation comprises a representation of fat metabolism. Claims 26 and 28 are amended to clarify that the simulation comprises a representation of protein metabolism. Support for these amendments can be found in the specification at paragraph [0008], paragraph [0021], paragraph [0034], paragraph [0037], and paragraph [0038].

Applicant submits that Tresp does not disclose a simulation of glucose metabolism comprising a representation of two of carbohydrate metabolism, fat metabolism and protein metabolism. This argument was presented in the paper submitted 14 November 2005. The Examiern traversed the argument stating:

> Determinant influencing variables for this blood sugar-insulin metabolism are, in detail, the times and dosage amounts of isulin injections, the times and amounts of food ingestion (basal insulin u_t^1 and normal insulin u_t^2), the times and amounts of food ingestions (fast ut3, <u>medium ut4</u> and **slow ut5 carbohydrates**), the points in time and duration of physical exercise (regular u_t^6 or intensive u_t^7) and the blood sugar level y_t (measured multiply per day).

> The above-above cited paragraph clearly shows two items from the group of carbohydrates, fats, and proteins; the two items are <u>medium,</u> and **slow** carbohydrates.

(Emphasis in original). Applicant submits that the Examiner has misconstrued the term "at least two from the group of". The Examiner merely has selected <u>one</u> item from the group twice. This is inconsistent with meaning of the phrase "at least two." In order for a simulation or plurality of biological processes to include a representation of two selected from the group consisting of carbohydrate metabolism, fat metabolism and protein metabolism, the simulation or plurality of biological processes must include (a) representations of carbohydrate metabolism and fat metabolism, (b) representations of carbohydrate metabolism and protein metabolism or (c) representations of fat metabolism and protein metabolism. Tresp fails to teach or suggest any one of combinations (a), (b) or (c).

Applicant admits that Tresp divides carbohydrates into three groups: slow, medium and fast. However, modeling slow carbohydrates and medium carbohydrates in no way teaches or suggests a model taking into consideration at least <u>two</u> of the three basic types of macronutrients, i.e. carbohydrates, fats and proteins. The Tresp model includes only one of these macronutrients, carbohydrates. Tresp is entirely silent with regard to fat metabolism and protein metabolism. Each of claims 1-9, and 20, directly or indirectly (by dependency) recites that the simulation or plurality of biological processes "comprises a representation of <u>two</u> macronutrient metabolisms

selected from the group consisting of fat metabolism, protein metabolism and carbohydrate metabolism." Accordingly, Applicant submits that Tresp, which describes only carbohydrate metabolism, does not anticipate claims 1-9, or 20.

The Examiner also rejects claims 25-28 as being anticipated by Tresp. Applicant submits that Tresp fails to teach the limitation requiring that the plurality of biological processes form a simulation in the context of fat metabolism or protein metabolism (as the claims previously recited) or a simulation that comprises a representation of fat metabolism or protein metabolism (as the claims recite as currently amended). The Examiner points to col. 3, equation 3, to col. 2, lines 10-23 and to col. 4, lines 33-41 in support of the rejection stating:

> Tresp's disclosure is broader than the limitations set forth by this claim.
> Hence, it covers biological attributes of diabetes in the context of fat
> metabolism [or protein metabolism for claims 26 and 28].

However, the appropriate criteria for establishing anticipation is not whether the "disclosure is broader than the limitations set forth in this claim," but rather a single prior art reference teaches, implicitly or explicitly, each and every limitation of the claim. Equation 3 contains no variable that is disclosed as representing fat metabolism or protein metabolism. Column 2, lines 10-23 state:

> In an embodiment of the method, the specified system equations are
> advantageously employed since this involves an optimally low
> calculating outlay in the training and in the simulation of the model.
>
> In an embodiment of the method, the dynamic system of the glucose-
> insulin metabolism of a diabetes patient can be advantageously
> modelled, whereby the glucose level of the patient is preferably
> modelled by the computerized neural network as the influencing variable
> and the error model is trained, since few values are available for this
> measured value as the influencing variable and the overall system
> behaves highly stochastically and non-linearly.

Column 4, lines 33-41 states:

> Determinant influencing variables for this blood sugar-insulin
> metabolism are, in detail, the times and dosage amounts of insulin
> injections, the times and amounts of food ingestion (basal insulin u_t^1 and

normal insulin u_t^2), the times and amounts of food ingestion (fast u_t^3, medium u_t^4 and slow u_t^5 carbohydrates), the points in time and duration of physical exercise (regular u_t^6 or intensive u_t^7) and the blood sugar level y_t (measured multiply per day).

None of the sections cited by the Examiner provide any disclosure of fat metabolism or protein metabolism, never mind the desirability of including representations of fat or protein metabolism in a computer model of diabetes. Because, Tresp does not disclose the inclusion of fat metabolism or protein metabolism in its model of diabetes, this reference cannot anticipate claims 25-28, each of which requires that the simulation comprise a representation of fat metabolism (claims 25 and 27) or protein metabolism (claims 26 and 28).

While Applicant respectfully disagrees with the Examiner's rejection of claims 1-9, 20 and 25-28 , because Tresp fails to teach at least the limitations "a <u>simulation</u> of glucose metabolism" and "a <u>simulation</u> of at least one biological attribute of diabetes" as required by claims 1, 7, and 25-28, Applicant submits that this basis of non-anticipation is mooted y the arguments presented above. Applicant's failure to extensively address the Examiner's interpretation of the term "simulation" as used in the claims of the current invention is not to be interpreted as acquiescence to the Examiner's position. Applicant reserves the right to address these arguments in this and other proceedings.

Applicant respectfully requests the Examiner to withdrawn the rejections under 35 U.S.C. § 102(e) in view of Tresp.

IV.   Rejection of Claims 10-15 Under 35 U.S.C. § 102(b)

The Examiner rejects claims 10-15 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 65,956,501 to Brown (hereinafter "Brown"). Claim 10 is amended to clarify that the set of biological processes being related to glucose metabolism refers to a set of biological processes comprising a representation of <u>two</u> macronutrient metabolisms selected from the group consisting of carbohydrate metabolism, fat metabolism and protein metabolism. Support for this amendment can be found in the specification at paragraph [0008], paragraph [0021], paragraph [0034], paragraph [0037], and paragraph [0038].

Applicant submits that Brown does not anticipate claims 10-15, as amended, because the reference fails to describe "defining a normal biological state through a set of biological processes, each biological process from the set of biological processes having its own associated parameter set, the set of biological processes being related to glucose metabolism in the context of multiple macronutrient metabolism, wherein the set of biological processes comprises a representation of two macronutrient metabolisms selected from the group consisting of fat metabolism, protein metabolism and carbohydrate metabolism," as required by Claim 10. Specifically, Applicant submits that Brown provides no disclosure of defining a biological state through a set of biological processes where that set of biological processes include representations of at least two of carbohydrate metabolism, fat metabolism and protein metabolism.

Brown discloses a system for predicting the effect of patient self-care actions on disease conditions, such as diabetes. However, nothing in the disclosure of Brown even alludes to fat metabolism or protein metabolism. Indeed, Brown does not even appear to model carbohydrate or glucose metabolism, but rather simulates just the clinical effects of certain actions such as insulin injection, diet, or exercise. Thus Brown fails to to teach or suggest the explicit inclusion of carbohydrate metabolism, fat metabolism or protein metabolism in the the set of biological processes that form part of the model of diabetes. Accordingly, Applicant submits that Brown does not anticipate claims 10-15.

While Applicant respectfully disagrees with the Examiner's rejection of claims 10-15 because Brown fails to teach at least the limitation "providing <u>a plurality of predefined defect indicators</u> each predefined defect indicator from the plurality of predefined defect indicators being uniquely associated with a defect from a plurality of defects associated with a disease state of diabetes" as required by claim 10 (emphasis added), Applicant submits that this basis of non-anticipation is mooted by the arguments presented above. Applicant's failure to extensively address the Examiner's interpretation of the term "defect indicator" vis-à-vis Brown is not to be interpreted as acquiescence to the Examiner's position. Applicant reserves the right to address these arguments in this and other proceedings.

Applicant respectfully requests the Examiner to withdrawn the rejections under 35 U.S.C. § 102(b) in view of Brown.

V.   Rejection of Claims 16-19 and 24 Under 35 U.S.C. § 102(e)

The Examiner rejected claims 16-19 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,246,975 to Rivonelli et al. (hereinafter Rivonelli). Applicants respectfully traverse this rejection. Claim 16 is amended to clarify that the set of biological processes being related to glucose metabolism refers to a set of biological processes comprising a representation of two macronutrient metabolisms selected from the group consisting of carbohydrate metabolism, fat metabolism and protein metabolism. Support for this amendment can be found in the specification at paragraph [0008], paragraph [0021], paragraph [0034], paragraph [0037], and paragraph [0038].

Applicant submits that Rivonelli does not anticipate claims 16-19 because this reference does not teach nor suggest the step of "providing a plurality of predefined defect indicators, each predefined defect indicator from the plurality of predefined defect indicators being uniquely associated with a defect from a plurality of defects associated with a disease state, each defect from the plurality of defects being associated with at least one biological process from a set of biological processes, the set of biological processes being related to glucose metabolism in the context of multiple macronutrient metabolism, wherein the set of biological processes comprises a representation of two macronutrient metabolisms selected from the group consisting of fat metabolism, protein metabolism and carbohydrate metabolism," as required by Claim 16, as amended. Specifically, Applicant submits that Rivonelli provides no disclosure of a set of biological processes where that set of biological processes include representations of at least two of carbohydrate metabolism, fat metabolism and protein metabolism.

Rivonelli describes a deterministic model designed to test the medical knowledge of physicians or those studying to become physicians. The model is based upon a knowledge base containing patterns and sub-patterns which depict in probabilistic terms disease/condition incidence, prevalence, evolution over time and response to interventions. See Rivonelli at

-20-

column 9, lines 17-26. The terms "carbohydrate,""fat," and "protein" do not appear in the specification, nor does the disclosure of Rivonelli implicitly refer to carbohydrate metabolism, fat metabolism or protein metabolism. Thus, Rivonelli fails to teach or suggest a model of diabetes which explicitly includes a set of biological processes that comprise representations of carbohydrate metabolism, fat metabolism or protein metabolism. Accordingly, Applicant submits that Brown does not anticipate claims 16-19.

Applicant also respectfully submit that Rivonelli fails to teach at least the limitation "providing a plurality of predefined defect indicators, each predefined defect indicator from the plurality of predefined defect indicators being uniquely associated with a defect from a plurality of defects associated with a disease state, each defect from the plurality of defects being associated with at least one biological process from a set of biological processes" as required by claim 16. (Emphasis added).

Rivonelli describes that "[t]he software of the present invention presents a patient by using text, illustrations, still pictures, and video. The examinee questions and examines the simulated patient, reaches conclusions about the situation, and suggests treatment options." (Rivonelli, Col. 12, lines 48-52). The Examiner specifically cites to Col. 6, lines 58-62 of Rivonelli as providing a teaching of a plurality of predefined defect indicators:

> Once presented with the patient description (age, race, sex, clinical findings), the candidate then selects appropriate COA's for further evaluation and/or management of the patient's health state. Selection of an interventional COA invokes pattern modifiers which evolve the patient's health state by implementing shape modifiers. These modifiers act upon the initially selected health state patterns to redefine the patient's health state or findings (e.g., a COA of insulin administration would alter the hyperglycemic finding specified in the health state descriptions for diabetes mellitus.)

(Rivonelli, Col. 6, lines 53-62; emphasis added). The cited passage of Rivonelli, however, fails to teach "a plurality of predefined defect indicators" even if hyperglycemia is both a defect and a defect indicator. Therefore, Rivonelli fails to teach at least the limitation "providing a plurality of predefined defect indicators, each predefined defect indicator from the plurality of predefined

-21-

defect indicators being uniquely associated with a defect from a plurality of defects associated with a disease state, each defect from the plurality of defects being associated with at least one biological process from a set of biological processes."

As a result, Rivonelli fails to disclose, suggest, or teach all of the limitations of claim 16. An anticipation rejection cannot properly be maintained where the references used in the rejection do not disclose all of the recited claim elements. Applicants respectfully traverse any arguments posed by Examiner relative to claims 17-19 as they are allowable for at least the reasons outlined above relative to claim 16. Therefore, Applicants respectfully request withdrawal of the rejection of claims 16-19.

VI.   Rejection of Claims 21-22 Under 35 U.S.C. § 103(a)

In the Office Action, claims 21 and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tresp and further in view of Rivonelli. Applicants respectfully traverse this rejection because Tresp and Rivonelli in combination fail to disclose, teach, or suggest all of the claim limitations as recited in Claims 21-22.

As discussed in Section III. above, Tresp fails to teach at least the limitation of "defining a plurality of biological processes related to a disease state of diabetes, wherein the plurality of biological processes comprises a representation of at least two macronutrient metabolisms selected from the group of fat metabolism, protein metabolism and carbohydrate metabolism" as required by claim 20, from which claims 21 and 22 depend. Rivonelli describes a "computer implemented simulation and evaluation method [that] simulates interventions to a patient by a user, and evaluates the interventions responsive to predetermined criteria and the interventions." (Rivonelli, Abstract). Rivonelli describes that "[a]gent descriptions include data about intake, metabolism, and excretion, as applicable." (Rivonelli, Col. 18, lines 24-25). Rivonelli makes no other mention of metabolism and fails to mention carbohydrates, fats, or proteins at all. As a result, neither Tresp nor Rivonelli disclose, suggest, or teach all of the limitations of claim 20. An obviousness rejection cannot be properly maintained where the references used in the

-22-

rejection do not disclose all of the recited claim elements. Therefore, Applicants respectfully request withdrawal of the rejection of claims 21 and 22 which depend from claim 20.

VII.   Rejection of Claim 23 Under 35 U.S.C. § 103(a)

In the Office Action, claim 23 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Tresp and further in view of AIDA 1 and AIDA 2. Applicants respectfully traverse this rejection because, at a minimum, the Examiner has failed to demonstrate that Tresp, AIDA 1, and AIDA 2, alone or in combination, disclose, teach, or suggest all of the claim limitations as recited in Claim 23.

As discussed in Section III. above, Tresp fails to teach at least the limitation of "defining a plurality of biological processes related to a disease state of diabetes, wherein the plurality of biological processes comprises a representation of at least two macronutrient metabolisms selected from the group of fat metabolism, protein metabolism and carbohydrate metabolism" as required by claim 20, from which claim 23 depends. AIDA 1 shows a carbohydrate input text box. (AIDA 1, page 3). AIDA 2 states "[d]epending on the carbohydrate content of the various meals and the amount of insulin injected, ..., the model is able to simulate a blood glucose profile." (AIDA 2, page 3). Neither AIDA 1 nor AIDA 2 mentions fats or proteins at all. As a result, neither Tresp, AIDA 1, nor AIDA 2 disclose, suggest, or teach all of the limitations of claim 20. An obviousness rejection cannot be properly maintained where the references used in the rejection do not disclose all of the recited claim elements. Therefore, Applicants respectfully request withdrawal of the rejection of claim 23 which depends from claim 20.

For the foregoing reasons, it is submitted that all of the claims that have been examined in this application should be in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-2350. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even

entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-2350. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-2350.

Respectfully submitted,

Date June 9, 2006

By _____

FOLEY & LARDNER LLP
Customer Number: 23524
Telephone: (608) 258-4263
Facsimile: (608) 258-4258

Callie M. Bell
Attorney for Applicants
Registration No. 54,989